

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT(S):** Robert F. CASPER, et al.

**U.S.S.N.:** -

**ART UNIT:** 1616 (presumed)

**FILED:** Herewith

**EXAMINER:** B. Badio (presumed)

**FOR:** LOW DOSE ESTROGEN INTERRUPTED HORMONE  
REPLACEMENT THERAPY

\*\*\*\*\*

**CERTIFICATE OF EXPRESS MAIL**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. **EV438991345US** addressed to: **MAIL STOP PATENT APPLICATION**, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on March 22, 2004.

By: 

Donna R. Davis

\*\*\*\*\*

**MAIL STOP PATENT APPLICATION**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II. COPIES

- a. \_\_\_\_\_ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. X\_\_\_\_\_ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. 09/538,485, filed on March 30, 2000, now abandoned, and application Serial No. 10/134,455, now pending. The following references were submitted to, and/or cited by, the Office in the prior application (s) and, therefore, are not required to be provided in this application.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

- a. \_\_\_\_\_ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. X\_\_\_\_\_ A concise explanation of the relevance of all patents, publications or other information listed that was cited in prior application no. 09/538,485, filed on March 30, 2000, now abandoned, that was not in the English language is as follows: Was attached by an English language Abstract for references identified as "AG" and "AH" (identified in this IDS as references "BD" and "BE").
- c. \_\_\_\_\_ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)  
(check one box)

- a. X\_\_\_\_\_ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1). No fee or certification is required.
- b. \_\_\_\_\_ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2). No fee or certification is required.

- c. \_\_\_\_\_ Before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. \_\_\_\_\_ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

or

- b. \_\_\_\_\_ See the certification below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. \_\_\_\_\_ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- b. \_\_\_\_\_ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.
- c. \_\_\_\_\_ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was

known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

\_\_\_\_\_ Please charge Deposit Account No. 04-1105 in the amount of \$180.00 for the above-indicated fee. A triplicate copy of this paper is attached.

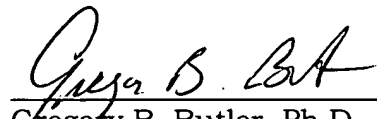
X\_\_\_\_\_ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule, with a petition if necessary, and charge the appropriate fee to Deposit Account No. **04-1105**.

Respectfully submitted,

Date: March 22, 2004

By:

  
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<b>FORM PTO-1449</b>  <b>INFORMATION DISCLOSURE STATEMENT</b>			<b>DOCKET NO.:</b> 58267-CON2(46453)		<b>SERIAL NO.:</b> -		
			<b>APPLICANT(S):</b> Robert F. CASPER, et al.				
			<b>FILING DATE:</b> Herewith		<b>GROUP NO.:</b> 1616 (presumed)		
<b>UNITED STATES PATENT DOCUMENTS</b>							
EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE IF APPROPRIATE
	AA	4,957,119	09-18-90	De Nijs	128	832	
	AB	5,088,505	02-18-92	De Nijs	128	830	
	AC	5,108,995	04/28/92	Casper	514	170	
	AD	5,256,421	10/26/93	Casper	514	170	
	AE	5,276,022	01/04./94	Casper	514	170	
	AF	5,382,573	01/17/95	Casper	514	170	
	AG	5,422,119	06/06/95	Casper	514	170	
	AH	5,585,370	12/17/96	Casper	514	170	
	AI	5,633,242	05/27/97	Oettel, et al.	514	170	
	AJ	6,133,251	10/17/00	Dittgen, et al.	514	170	
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES/NO
	BA	EP 0 309 263	03.29.89	EUROPE			Yes
	BB	WO 97/11680	04.03.97	WIPO			Yes
	BC	EP 0 275 716	07.27.88	EUROPE			Yes
	BD	EP 0 770 388	05.02.97	EUROPE			Abstract also see U.S. 6,133,251
	BE	DE 44 29 374	02.01.96	GERMANY			Abstract also see U.S. 5,633,242
	BF	WO 98/37897	09.03.98	WIPO			Yes
<b>OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)</b>							
	CA	Lobo, et al., "A novel intermittent regimen of norgestimate to preserve the beneficial effects of 17β-estradiol on lipid and lipoprotein profiles," Am. J. of Obstet. & Gynecol., Vol. 182, No. 1, Part 1, January 2000, pp. 41-49 (XP-000900454).					
	CB	Sulak, et al., "Efficacy and Safety of a Constant-Estrogen, Pulsed-Progestin Regimen in Hormone Replacement Therapy," Int'l. Journal of Fertility and Women's Medicine, Nov-Dec. 1999, pp. 286-296 (XP-000934379).					
	CC	Vanin, et al., "Lumbar vertebral density and mechanical properties in aged ovariectomized rats treated with estrogen and norethindrone or norgestimate," Am. J. of Obstet. & Gynecol., Vol. 173, No. 5, November 1995, pp. 1491-1498 (XP-000934383).					
	CD	Christin-Matrie, et al., "Perceptives de la contraception," La Revue du Practicien, 1995, pp. 2449-2453 (English abstract on p. 2453 (last page)).					
<b>EXAMINER:</b>					<b>DATE:</b>		